K111162

Dentium

JAN 13 2012

510(k) Summary

12/14/2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

1. Company

	Submitter	Official Correspondent
Name	Dentium Co., Ltd.	Dentium USA
Address	27-5 Iui-dong, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-766, Korea	6761 Katella Avenue Cypress, CA 90630, USA
Phone	+82-31-207-2200	714-226-0229
Fax	+82-31-207-3883	714-226-0019
Contact person	Lee, Sungwon / R&D swlee@dentium.com	Eunkyung Son / Doctor json@dentiumusa.com

2. Device Name

Proprietary name: Slim Onebody System
Common name: Endosseous Dental Implant
Classification name: Implant, Endosseous, Root-Form
Product Code: DZE
Regulation Number: 21CFR872.3640
Device Class: Class II

3. Predicated Device

K031106 IMTEC, Sendax MDI and MDI Plus

4. Description

The Slim Onebody System is a mini implant made of Ti-6Al-4V ELI alloy(ASTM F136) and Pure Titanium Gr4(ASTM F67). It serves as a temporary support for provisional prosthetic device during the healing phase of permanent endosseous

dental implantation. Its surface is S.L.A(Sand-Blasted, Large Grit, Acid-etched). It is comprised of diameter ranging from 2.0 – 3.0mm and lengths ranging from 10mm – 14mm. The product consists of a FIX type and a Ball Type implant.

5. Substantial Equivalence

Trade name	Slim Onebody System	Sendax MDI
Manufacturer	Dentium Co., Ltd.	IMTEC(SENDAX)
510(k) Number	New device	K031106
Materials	Titanium Alloy	Titanium, Titanium Alloy
Form	Root-Form, Threaded	Root-Form, Threaded
Sterilization	Sterile	Sterile
Length	10mm~14mm	10mm~18mm
Diameter	2.0 ~ 3.0	1.8 ~ 2.4
Indications for use	The Slim Onebody System is intended for immediate loading in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase (maximum six months) of permanent endosseous dental implants.	The MDI and MDI PLUS are self-tapping titanium thread screws indicated for long-term intra-bony applications. Additionally, the MDI may also be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full partial endentulism, and employing minimally invasive surgical intervention.
Use	Prescription	Prescription

Raw material, mechanical and physical properties, shape, and intended use are similar to the predicated devices. The differences between Slim Onebody and predicate devices are the slight mechanical and physical characteristics. However, the slight differences do not affect the application of the device. Therefore, we state that Slim Onebody is substantial equal with the predicate devices.

6. Indication for Use

The Slim Onebody System is intended for immediate loading in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase (maximum six months) of permanent endosseous dental implants.

7. Non-Clinical Testing

Non-clinical test data was used to support the decision of safety and effectiveness. Non-clinical testing consisted of performance of fatigue testing in accordance with the FDA guidance Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments.

Biocompatibility testing on the proposed Slim Onebody System has been completed. Requirements for biological evaluation of the proposed device were based on the ISO7405 (2008), "Dentistry-Evaluation of biocompatibility of medical devices used in dentistry." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed:

-ISO Cytotoxicity	-ISO Systemic toxicity
-ISO Pyrogencity	-ISO Sensitization
-ISO Intracutaneous reactivity	-ISO Implantation

The proposed Slim Onebody System was evaluated using the following performance bench testing to confirm the performance characteristics:

-ISO Static compressive	-ISO Fatigue
-Torque Force	

The testing indicates that the device is strong enough to withstand the anticipated forces

8. Clinical Testing

Non-clinical test data was used to support the decision of safety and effectiveness.

9. Review

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the Slim Onebody System met the established specifications necessary for consistent performance according to its intended use.

Slim Onebody System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

10. Conclusions

All of the data consistent with the recommendations in the FDA guidance document Root-form Endosseous Dental Implants testing of the implants demonstrated that the Slim Onebody System is substantially equivalent to the predicate device implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dentium Company, Limited
C/O Dr. Eunkyung Son
Dentium USA
6761 Katella Avenue Cypress
Cypress, California 90630

JAN 13 2012

Re: K111162
Trade/Device Name: Slim Onebody System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: DZE
Dated: December 20, 2011
Received: December 21, 2011

Dear Dr. Son:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Dentium

Indications for Use

510(k) Number: k111162

Device Name: Slim Onebody System

Indications for Use:

The Slim Onebody System is intended for immediate loading in partially or fully edentulous mandibles and maxillae to serve as temporary support for provisional prosthetic device during the healing phase (maximum six months) of permanent endosseous dental implants.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111162